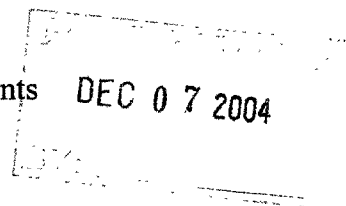




November 30, 2004

The Office of Nutritional Products, Labeling, and Dietary Supplements
Division of Nutrition Programs and Labeling (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



Title: New Product - Food Labeling; Notification Procedures for Statements on Dietary Supplements

Dear Whom It May Concern:

We are going to launch a new product in January, 2005. We're going to sell it with three different product names (GlucoPro™, Carbs-Check™, or GlyCotrol™: please refer to the attached) through our two companies:

- Sedona Laboratories, Inc. (211 Jennifer Lane, Cottonwood, AZ 86326, 1-888-816-8804) will sell GlucoPro™ and Carbs-Check™.
- Nutri-Health (218 Justin Drive, Cottonwood, AZ 86326, 1-800-914-6311) will sell GlyCotrol™.

The new product has the following ingredients:

1. Chaga Mushroom Extract (CHP7), *Inonotus obliquus*
2. Matrimony Vine Extract, *Lycium chinensis*
3. Red Ginseng Extract, *Panax ginseng*
4. Mulberry Leaves Extract, *Mori folium*
5. Mulberry Fruits Extract, *Mori folium*

GlyCotrol™ has been sold in Korea as a dietary supplement, coated rice, and tea since 2002 with the brand name of Sodangmi™ and Sodang Extract™ by RNL Life Science, Ltd. RNL is a research-oriented biotech company in Korea, and has studied the efficacy and safety of each ingredient since 2001. They have published two articles about the efficacy and safety of Sodangmi™ and Sodang Extract™ (Journal of Korean Society of Food Science Nutrition (2003), Vol. 32(4), pp 614-620 and Korean Journal of Oriental Physiology & Pathology (2003), Vol. 17(1), pp 130-134). According to the published articles, Sodangmi™ and Sodang Extract™ showed hypoglycemic effect by controlling digestive enzymes in in-vitro tests, animal tests and two clinical studies. Please refer to the attached Reference 1 and 2 for details. RNL published the inhibitory effect of chaga mushroom (*Inonotus obliquus*) on digestive enzymes such as

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Sedona Labs, Inc.

211 Jennifer Drive • Cottonwood, AZ 86326

tel: (888) 816-8804 • fax: (866) 887-8489

www.sedonalabs.com



glucosidase and lipase (Figure 1 & 2 in Reference 3). Mulberry (*Folium mori* or *Morus indica*) leaves and fruits have been known to maintain normal blood sugar levels. There are a lot of published articles about its hypoglycemic efficacy (Reference 4~12). In addition, red ginseng and matrimony vine are proved to be effective to control blood sugar profiles (Reference 13~31).

I also have attached the following additional documents to substantiate that the GlucoPro™, Carbs-Check™, and GlyCotrol™ labels are based on facts and studies published in science journals and magazines.

1. The New Product Labels
2. Published Article (Reference 1~31)
3. Certificate of Patent application
4. Food (Food Additives) Manufacturing Report; to substantiate that the new product is manufactured under Korean FDA rules and registered as food by Korean FDA.
5. Clinical and Pre-clinical Study Summary

I certify that all of the information and the attached data presented in this notice are accurate and truthful. If I can be of any assistance, please contact me at mokang@sedonalabs.com or 1-800-914-6311.

Sincerely yours,

Mo Kang, MBA, MS

Senior Scientist

New Product Development Department

Sedona Laboratories, Inc.

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